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**UNITED STATES DISTRICT COURT**  
**NORTHERN DISTRICT OF CALIFORNIA**  
**SAN FRANCISCO DIVISION**

MELISSA MCEVOY, individually and as	)	Case No. 3:22-cv-3602
mother and general guardian of P.N., a minor,	)	
	)	<b>COMPLAINT</b>
<i>Plaintiffs,</i>	)	<b>(Jury Trial Demanded)</b>
	)	
v.	)	
	)	
TARGET CORPORATION	)	
	)	
<i>Defendant.</i>	)	
	)	

1 Plaintiff Melissa McEvoy and, pursuant to Fed. R. Civ. P. 17(c)(1)(A), Plaintiff P.N., a  
2 minor, by and through their undersigned counsel, bring this Complaint for damages against  
3 Defendant Target Corporation, (hereinafter, “Target” or “Defendant”) and in support allege the  
4 following:

5 1. This is an action brought on behalf of Plaintiffs Melissa McEvoy (hereinafter,  
6 “Plaintiff Mother”), the mother and guardian of P.N. (hereinafter, “Plaintiff Child”), a minor,  
7 arising out of the failure of Defendant to warn about the dangers of prenatal exposure to  
8 Paracetamol, also known as Acetaminophen (hereinafter “APAP”) and its propensity to cause  
9 autism spectrum disorder (hereinafter, “ASD”) in children. As a result, Plaintiffs have suffered  
10 permanent injuries and significant pain and suffering, emotional distress, lost wages and earning  
11 capacity, and diminished quality of life. Plaintiffs respectfully seek all damages to which they  
12 may be legally entitled.

13 2. Defendant entirely failed its duty to adequately warn of the hazards of prenatal  
14 exposure to APAP, which was a direct and proximate cause of Plaintiffs’ injuries and associated  
15 damages.

### 16 **PARTIES**

17 3. At all material times Plaintiffs have been citizens and residents of Contra Costa  
18 County, California, and the United States.

19 4. Target is incorporated in Minnesota, with its principal place of business also in  
20 Minnesota.

21 5. Target is a multinational company involved in the research, development, testing,  
22 manufacture, labeling, production, marketing, promotion, and/or sale of APAP through its over-  
23 the-counter store brand, “Up & Up” (hereinafter, the “Up & Up APAP”).

24 6. Target is individually, and jointly and severally liable to Plaintiffs for damages they  
25 suffered, arising from Defendant’s design, manufacture, marketing, labeling, distribution, sale, and  
26 placement of the defective Up & Up APAP into the market, effectuated directly and indirectly  
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1 through its agents, servants, employees, and/or owners, all acting within the course and scope of  
 2 its agencies, services, employments, and/or ownership.

3 7. Target is vicariously liable for the acts and/or omissions of its employees and/or  
 4 agents, who were at all material times acting on behalf of Target and within the scope of its  
 5 employment or agency.

### 6 **VENUE AND JURISDICTION**

7 8. This Court has subject-matter jurisdiction under 28 U.S.C. § 1332(a), based on  
 8 complete diversity of citizenship between Plaintiffs and Defendant. *See supra* ¶¶ 3–4.

9 9. The amount in controversy exceeds \$75,000.

10 10. Venue is proper in this Court pursuant to 28 U.S.C. § 1391 because the events or  
 11 omissions giving rise to Plaintiffs' claims occurred in this judicial district.

12 11. Defendant has and continues to conduct substantial business in the State of  
 13 California and in this District, distributes the Up & Up APAP in this District, receives substantial  
 14 compensation and profits from sales of the Up & Up APAP in this District, and has made material  
 15 omissions and misrepresentations and breaches of warranties in this District, so as to subject  
 16 Defendant to in personam jurisdiction in this District.

17 12. Defendant is registered to transact business in California.

### 18 **INTRADISTRICT ASSIGNMENT**

19 13. This matter is properly assigned to the San Francisco Division of this District  
 20 pursuant to Civil Local Rules 3-2(c) and 3-2(d) because Defendant maintains retail stores in  
 21 Contra Costa County and other counties within the San Francisco Division, and Plaintiffs reside  
 22 in Contra Costa County. Therefore, because Defendant maintains retail stores in Contra Costa  
 23 County, a substantial part of the events or omissions that give rise to the claims occurred within  
 24 this Division within the meaning of Civil Local Rule 3-2(c), and are properly assigned to this  
 25 Division pursuant to Civil Local Rule 3-2(d).  
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 27  
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**FACTS COMMON TO ALL COUNTS**

**APAP Is Marketed as the Safe Pain Reliever for Pregnant Women,  
but APAP Can Cause Neurodevelopment Disorders in Children, such as ASD**

13. APAP was initially discovered in the late 1800's.

14. APAP is sold in billions of units annually in North America alone.

15. APAP is widely used by pregnant women to relieve pain during the term of their pregnancy.

16. APAP was introduced to the US market in 1955 as the first aspirin-free pain reliever.

17. APAP has long been marketed as the safest, and the *only* appropriate, over-the-counter pain relief drug on the market for pregnant women.

18. More than 65% of women in the United States use APAP during pregnancy.

19. Based upon information and belief, a majority of women who use APAP during pregnancy do so electively for the treatment of headaches, muscle pain, back pain, and infection.

20. These pregnant women electively choose to take APAP because Defendant has marketed APAP as a safe pain reliever for pregnant women.

21. However, increasing experimental and epidemiological research shows that prenatal exposure to APAP alters fetal development, which significantly increases the risks of neurodevelopmental disorders, including but not limited to, autism spectrum disorder ("ASD") and attention-deficit/hyperactivity disorder.

22. Undisturbed development of the human brain in utero is vital to the health and wellness of a child's development. The human brain is vulnerable and extremely sensitive in utero.

23. During this sensitive time-period in utero, certain chemicals have been found to cause permanent brain injury at low exposure levels.

24. Once ingested by the mother, APAP is known to readily cross the placenta and blood-brain barrier.

1           25.     ASD is a serious neurological and developmental disorder that affects how people  
2 interact with others, communicate, learn, and behave.

3           26.     There are three functional levels of ASD, with Level 1 requiring support with  
4 activities of daily living, Level 2 requiring substantial support with activities of daily living, and  
5 Level 3 requiring very substantial support with activities of daily living.

6           27.     Treatments for ASD include behavioral management therapy, cognitive behavior  
7 therapy, joint attention therapies, medications, occupational therapy, physical therapy, social skill  
8 training, and speech-language therapy. Treatment for ASD lasts a lifetime, as there is no cure.

9           28.     In or around 2018, the Center for Disease Control and Prevention (“CDC”) found  
10 that 1 in 44 (2.3%) 8-year-old children have been diagnosed with ASD.

11           29.     This represents an increase from a prior CDC finding that 1 in 68 U.S. children  
12 born in 2002 have ASD, which already represented a more than a 100% increase compared with  
13 children born a decade prior.

14           30.     Parental awareness and changes in diagnoses do not account for the rapid rise in  
15 these diagnoses of ASD.

16           31.     Rather, neurotic exposures, such as prenatal APAP exposure, explain a trending  
17 increase in diagnosis.

18           32.     For years, the scientific community has published studies showing that prenatal  
19 ingestion of APAP can cause ASD.

20           33.     For instance, since 2013, there have been six European birth cohort studies,  
21 examining over 70,000 mother-child pairs, showing the association between prenatal use of APAP  
22 and ASD and attention-deficit/hyperactivity disorder (“ADHD”).

23           34.     At this time, the overall body of scientific evidence shows that prenatal use of  
24 APAP can cause ASD in the child.

25           35.     During all relevant times herein, Defendant was engaged in the business of  
26 manufacturing and selling the APAP Products in the United States, and the weight of the scientific  
27 evidence available showed prenatal exposure to APAP significantly increases the risk of  
28

1 neurodevelopmental disorders in children exposed to APAP prenatally, including but not limited  
2 to ASD.

3 36. The scientific evidence regarding the risks of in utero exposure of APAP was  
4 available to Defendant, and Defendant knew or should have known that prenatal use of APAP can  
5 cause ASD.

6 37. Based on information and belief, Defendant has concealed the prenatal APAP  
7 exposure-neurodevelopmental link from consumers, like Plaintiff Mother, in part by not reporting  
8 the link to the FDA, which relies on drug manufacturers to bring new information about a drug to  
9 the agency's attention.

10 38. Moreover, despite knowing that prenatal use of APAP can cause ASD, Defendant  
11 continues to market the APAP Products as the safe pain reliever for pregnant women, making  
12 mothers believe they are choosing a safe drug for even minor aches, pains, and headaches.

13 //

14 **Plaintiff Mother Took Up & Up APAP while Pregnant,**  
15 **and It Caused ASD in Plaintiff Child**

16 39. Plaintiff Mother began using the Up & Up APAP in or around January 2010, when  
17 she was pregnant with Plaintiff Child, through October 2010 when Plaintiff Child was born.

18 40. Throughout Plaintiff Mother's pregnancy, she took the Up & Up APAP a few times  
19 a month to treat headaches.

20 41. Plaintiff Mother purchased and took the Up & Up APAP in Contra Costa County,  
21 California.

22 42. Plaintiff Mother electively took the Up & Up APAP while pregnant.

23 43. Plaintiff Mother believed it was safe for her to take the Up & Up APAP during her  
24 pregnancy.

25 44. There is no warning on the Up & Up APAP labels specifically addressing the risks  
26 of a child developing ASD if a mother ingests APAP while pregnant.

27 45. Had Plaintiff Mother known of the risk of taking APAP while pregnant, specifically  
28

1 that it could cause ASD in her child, she would not have taken the Up & Up APAP.

2 46. Plaintiff Child was born on October 8, 2010.

3 47. Plaintiff Mother started to have concerns about Plaintiff Child's development when  
4 he was around four years old.

5 48. At that time, Plaintiff Child had become very aggressive.

6 49. Plaintiff Child was diagnosed with ASD when he was four years old.

7 50. Plaintiff Mother abandoned her career in order to devote more attention to Plaintiff  
8 Child because of his ASD.

9 51. Plaintiff Child is aggressive and can be a danger to himself and others because of  
10 his ASD.

11 52. Plaintiff Child attends behavioral therapy because of his ASD.

12 53. These issues have a huge impact on Plaintiff Mother and Plaintiff Child.

13 54. Plaintiff Child's ASD has placed an incredible strain on Plaintiff Mother.

14 **ESTOPPEL AND TOLLING OF STATUTE OF LIMITATIONS**

15 55. Due to Defendant's acts of fraudulent concealment, Defendant is estopped from  
16 relying on any statutes of limitations or repose. Such acts include Defendant's intentional  
17 concealment from Plaintiff Mother and the general public that APAP is defective when there is  
18 prenatal exposure, while continuing to market the Up & Up APAP with the adverse effects  
19 described in this Complaint.

20 56. Given Defendant's affirmative actions of concealment by failing to disclose  
21 information about the defects known to them but not the public—information over which  
22 Defendant had exclusive control—and because Plaintiff Mother could not reasonably have known  
23 that the Up & Up APAP was defective, Defendant is estopped from relying on any statutes of  
24 limitations that might otherwise be applicable to the claims asserted in this Complaint.

25 **COUNT I: STRICT LIABILITY – FAILURE TO WARN**

26 57. Plaintiffs incorporate by reference the allegations in all prior paragraphs.  
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1           58. At the time of Plaintiffs' injuries, the Up & Up APAP was defective and  
2 unreasonably dangerous to foreseeable consumers, including Plaintiff Mother, because they lacked  
3 an adequate warning.

4           59. At all relevant times, Defendant engaged in the business of testing, developing,  
5 designing, manufacturing, marketing, labeling, selling, distributing, and promoting the Up & Up  
6 APAP, which was defective and unreasonably dangerous to consumers, including Plaintiff Mother,  
7 because they did not contain adequate warnings or instructions concerning the dangerous  
8 characteristics of ingesting APAP during pregnancy. These actions were under the ultimate  
9 control and supervision of Defendant. At all relevant times, Defendant registered, researched,  
10 manufactured, distributed, marketed, labeled, promoted, and sold the Up & Up APAP within this  
11 District and aimed the marketing at the ultimate consumer. Defendant was at all relevant times  
12 involved in the retail and promotion of the Up & Up APAP marketed and sold in this District.

13           60. Defendant had a duty to warn of the risks associated with the use of the Up & Up  
14 APAP.

15           61. The Up & Up APAP ingested by Plaintiff Mother during pregnancy was in the same  
16 or substantially similar condition as it was when it left possession of the Defendant.

17           62. Defendant expected and intended the Up & Up APAP to reach users such as  
18 Plaintiff Mother in the condition in which the Up & Up APAP was sold.

19           63. Plaintiff Mother did not materially alter the Up & Up APAP prior to ingestion.

20           64. Plaintiff Mother ingested the Up & Up APAP as indicated on the Up & Up APAP  
21 labels.

22           65. Plaintiff Mother was unaware of the defects and dangers of the Up & Up APAP  
23 and was unaware that prenatal exposure increases the risk of brain and behavioral development of  
24 children in utero.

25           66. The labels on the Up & Up APAP to consumers lack any warning specific to  
26 pregnant women. The information that Defendant did provide or communicate failed to contain  
27 relevant warnings, hazards, and precautions that would have enabled consumers such as Plaintiff  
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1 Mother to utilize the products safely and with adequate protection, or decide to not ingest the Up  
2 & Up APAP at all.

3 67. This alleged failure to warn is not limited to the information contained on the Up  
4 & Up APAP' labeling. Defendant was able, in accord with federal law, to comply with relevant  
5 state law by disclosing the known risks associated with APAP through other non-labeling  
6 mediums, i.e., promotion, advertisements, public service announcements, and/or public  
7 information sources. But Defendant did not disclose these known risks through any medium.

8 68. At all relevant times, Defendant had a duty to properly test, develop, design,  
9 manufacture, inspect, package, label, market, promote, sell, distribute, maintain, and supply the  
10 Up & Up APAP; provide proper warnings for the Up & Up APAP; and take such steps as necessary  
11 to ensure the Up & Up APAP did not cause users and consumers, and their children, to suffer from  
12 unreasonable and dangerous risks. Defendant had a continuing duty to warn Plaintiff Mother of  
13 dangers associated with APAP. Defendant, as a manufacturer, seller, and/or distributor of  
14 pharmaceutical medication, is held to the knowledge of an expert in the field.

15 69. At the time of manufacture, Defendant could have provided the warnings or  
16 instructions regarding the full and complete risks of the Up & Up APAP because Defendant knew  
17 or should have known of the unreasonable risks of ASD associated with prenatal exposure to  
18 and/or the use of such products.

19 70. At all relevant times, Defendant failed and deliberately refused to investigate,  
20 study, test, or minimize the dangers to consumers of the Up & Up APAP and to those who would  
21 foreseeably use or be harmed by the Up & Up APAP, including Plaintiffs.

22 71. Defendant failed to adequately warn consumers, like Plaintiff Mother, about the  
23 significant increased risk of neurodevelopmental disorders in children exposed to APAP  
24 prenatally, including but not limited to ASD.

25 72. Defendant failed to adequately inform reasonably foreseeable consumers, like  
26 Plaintiff Mother, of the proper usage of the Up & Up APAP.

1           73. Even though Defendant knew or should have known that APAP posed a grave risk  
2 of harm to Plaintiff Child, Defendant failed to exercise reasonable care to warn of the dangerous  
3 risks associated with use and prenatal exposure.

4           74. Plaintiff Mother was exposed to the Up & Up APAP without knowledge of their  
5 dangerous characteristics.

6           75. At all relevant times, Plaintiff Mother used and/or was exposed to the use of the Up  
7 & Up APAP while using them for their intended or reasonably foreseeable purposes, without  
8 knowledge of their dangerous characteristics.

9           76. Plaintiff Mother could not have reasonably discovered the defects and risks  
10 associated with the Up & Up APAP prior to or at the time of Plaintiff consuming APAP. Plaintiff  
11 Mother relied upon the skill, superior knowledge, and judgment of Defendant to know about and  
12 disclose serious health risks associated with using the Up & Up APAP.

13           77. If Plaintiff Mother had been properly warned of the defects, dangers, and risks  
14 associated with prenatal exposure to APAP, Plaintiff Mother would have decided to not ingest the  
15 Up & Up APAP while pregnant.

16           78. Defendant is liable to Plaintiffs for injuries caused by Defendant's negligent or  
17 willful failure, as described above, to provide adequate warnings or other relevant information and  
18 data regarding the appropriate use of the Up & Up APAP and the risks associated with the use of  
19 APAP.

20           79. As a direct and proximate result of Defendant placing defective Up & Up APAP  
21 into the stream of commerce, and Plaintiff Mother's ingestion of the Up & Up APAP during  
22 pregnancy, Plaintiff Child was exposed to APAP prenatally, causing her to develop ASD.

23           80. As a direct and proximate result of Defendant placing defective Up & Up APAP  
24 into the stream of commerce, Plaintiffs have suffered permanent injuries, significant pain and  
25 suffering, emotional distress, lost wages and earning capacity, and diminished quality of life.  
26 Plaintiffs respectfully seek all damages to which they may be legally entitled.

27                           **COUNT II: NEGLIGENCE**  
28

1           81.     Plaintiffs incorporate by reference the allegations in all prior paragraphs.

2           82.     Although Defendant had a duty to use reasonable care in testing, developing,  
3 designing, manufacturing, marketing, labeling, selling, distributing, promoting, and preparing  
4 written instructions and warnings for the Up & Up APAP, Defendant failed to do so.

5           83.     Defendant, directly or indirectly, caused the Up & Up APAP to be sold, distributed,  
6 packaged, labeled, marketed, promoted, and/or used by Plaintiff Mother. At all relevant times,  
7 Defendant registered, researched, manufactured, distributed, marketed, promoted, and sold the Up  
8 & Up APAP within this district and aimed at a consumer market within this district.

9           84.     Defendant knew, or in the exercise of reasonable care should have known, that the  
10 Up & Up APAP was defectively and unreasonably designed and/or manufactured, and/or  
11 marketed, and was unreasonably dangerous and likely to injure persons that were prenatally  
12 exposed to them. Defendant knew or should have known that Plaintiff Mother was unaware of the  
13 dangers and defects inherent in the Up & Up APAP when she was ingesting them during her  
14 pregnancy with Plaintiff Child.

15           85.     At all relevant times, Defendant had a duty to exercise reasonable care in the  
16 marketing, advertisement, promotion, and sale of the Up & Up APAP. Defendant's duty of care  
17 owed to consumers and the general public included providing accurate, true, and correct  
18 information concerning the risks of using APAP during pregnancy and appropriate, complete, and  
19 accurate warnings concerning the potential adverse effects of APAP and, in particular, the  
20 significantly increased risk of causing neurodevelopmental disorders in children through prenatal  
21 exposure to APAP.

22           86.     At all relevant times, Defendant knew or, in the exercise of reasonable care, should  
23 have known of the hazards and dangers of APAP ingestion while pregnant and, specifically, the  
24 significantly increased risk of causing neurodevelopmental disorders in children through prenatal  
25 exposure to APAP.

1           87. Defendant failed to provide any kind of warning to pregnant consumers, like  
2 Plaintiff Mother, about the significantly increased risk of causing neurodevelopmental disorders  
3 in children through prenatal exposure to APAP.

4           88. Accordingly, at all relevant times, Defendant knew or, in the exercise of reasonable  
5 care, should have known that use of the Up & Up APAP could cause Plaintiffs' injuries, and thus,  
6 create a dangerous and unreasonable risk of injury to the users of these products, including  
7 Plaintiffs.

8           89. As such, Defendant breached its duty of reasonable care and failed to exercise  
9 ordinary care in the design, research, development, manufacture, testing, marketing, labeling,  
10 supply, promotion, advertisement, packaging, sale, and distribution of the Up & Up APAP, in that  
11 Defendant manufactured and produced defective Up & Up APAP, which carry the significantly  
12 increased risk of causing neurodevelopmental disorders in children through prenatal exposure to  
13 APAP; knew or had reason to know of the defects inherent in the Up & Up APAP; knew or had  
14 reason to know that a user's or consumer's use of the Up & Up APAP created a significant risk of  
15 harm and unreasonably dangerous side effects; and failed to prevent or adequately warn of these  
16 risks and injuries.

17           90. Defendant had a duty to disclose the truth about the risks associated with APAP in  
18 its promotional efforts outside of the context of labeling. Defendant was negligent in its promotion  
19 of APAP outside of the labeling context by failing to disclose material risk information as part of  
20 its promotion and marketing of the Up & Up APAP, including through the internet, television, and  
21 print advertisements.

22           91. Despite Defendant's ability and means to investigate, study, and test the Up & Up  
23 APAP and to provide adequate warnings, Defendant failed to do so. Indeed, Defendant wrongfully  
24 concealed information and further made false and/or misleading statements concerning the safety  
25 and use of APAP.

26           92. Defendant's negligence included:  
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- a. Manufacturing, producing, promoting, formulating, creating, developing, designing, selling, and/or distributing the Up & Up APAP while negligently and/or intentionally concealing and failing to disclose the results of trials, tests, and studies of APAP and the significantly increased risk of causing neurodevelopmental disorders in children through prenatal exposure to APAP, and, consequently, the risk of serious harm associated with human use of APAP during pregnancy;
- b. Failing to undertake sufficient studies and conduct necessary tests to determine whether or not the Up & Up APAP were safe for its intended consumer use and unborn children;
- c. Failing to provide adequate instructions, guidelines, and safety precautions to those persons Defendant could reasonably foresee would use the Up & Up APAP;
- d. Failing to disclose to Plaintiff Mother, users, consumers, and the general public that use of APAP during pregnancy presents severe risks of neurodevelopmental disorders in children exposed to APAP prenatally;
- e. Failing to warn Plaintiff Mother, users, consumers, and the general public that the Up & Up APAP' risk of harm was unreasonable and that there were safer and effective alternative medications or treatments available to Plaintiff Mother and other users and/or consumers;
- f. Representing that the Up & Up APAP were safe for their intended purposes for pregnant women when, in fact, Defendant knew or should have known the Up & Up APAP was not safe for their intended purposes;
- g. Declining to make or propose any changes to the Up & Up APAP' labeling or other promotional materials that would alert users, consumers, and the general public of the risks of APAP, including to pregnant women;
- h. Advertising, marketing, and recommending the use of the Up & Up APAP, while concealing and failing to disclose or warn of the dangers known by Defendant to be caused by the use of or exposure to APAP;

i. Continuing to disseminate information to its consumers and the general public, which indicates or implies that the Up & Up APAP are not unsafe for pregnant consumer use; and

j. Continuing the manufacture and sale of the Up & Up APAP with the knowledge that the Up & Up APAP was unreasonably unsafe and dangerous.

93. Defendant knew and/or should have known that it was foreseeable that children such as Plaintiff Child would suffer injuries as a result of Defendant's failure to exercise ordinary care in the manufacturing, marketing, labeling, distribution, and sale of the Up & Up APAP to consumers, like Plaintiff Mother.

94. Plaintiff Mother did not know the nature and extent of the injuries that could result in her child from the intended use of and/or exposure to APAP prenatally.

95. Defendant's negligence was the proximate cause of Plaintiffs' injuries, i.e., absent Defendant's negligence, Plaintiff Child would not have developed ASD.

96. Defendant's conduct, as described above, was reckless. Defendant regularly risked exposing Plaintiff Mother to the Up & Up APAP while pregnant with Plaintiff Child, with full knowledge of the dangers of the Up & Up APAP and that it could cause ASD in Plaintiff Child. Defendant made conscious decisions not to redesign, re-label, warn, or inform the unsuspecting public, including Plaintiff Mother. Defendant's reckless conduct therefore warrants an award of punitive damages.

97. As a direct and proximate result of Defendant placing the defective Up & Up APAP into the stream of commerce, Plaintiffs have suffered permanent injuries, significant pain and suffering, emotional distress, lost wages and earning capacity, and diminished quality of life. Plaintiffs respectfully seek all damages to which they may be legally entitled.

### **COUNT III: BREACH OF EXPRESS WARRANTY**

98. Plaintiffs incorporate by reference the allegations in all prior paragraphs.

1           99. At all material times, Defendant manufactured, marketed, sold, distributed, and  
2 otherwise placed into the stream of commerce the Up & Up APAP. These actions were under the  
3 ultimate control and supervision of Defendant.

4           100. In advertising, marketing, and promoting the Up & Up APAP to consumers, like  
5 Plaintiff Mother, Defendant expressly warranted that the Up & Up APAP was safe for use and  
6 reasonably fit for their intended purposes. In advertising, marketing, and otherwise promoting the  
7 Up & Up APAP, Defendant intended for pregnant consumers to rely upon its representations  
8 regarding safety and fitness, in an effort to induce them to purchase and consume the Up & Up  
9 APAP during pregnancy to relieve pain.

10           101. Defendant expressly warranted to Plaintiff Mother and pregnant consumers that the  
11 Up & Up APAP was safe for ingestion during pregnancy.

12           102. Defendant had a duty to exercise reasonable care in the research, development,  
13 design, testing, packaging, manufacture, inspection, labeling, distributing, marketing, promotion,  
14 sale, and release of the Up & Up APAP, including a duty to:

- 15           a. ensure that the Up & Up APAP did not cause users and their unborn children  
16           unreasonably dangerous side effects;  
17           b. warn of dangerous and potentially incurable side effects; and  
18           c. disclose adverse material facts, such as the true risks associated with the use of and  
19           exposure to APAP during pregnancy, when making representations to users,  
20           consumers, and the general public, including Plaintiff Mother.

21           103. Defendant had the ability to properly disclose the risks associated with APAP usage  
22 during pregnancy through multiple channels, not just labeling.

23           104. At all relevant times, Defendant expressly represented and warranted to the  
24 purchasers of the Up & Up APAP, by and through statements made by Defendant in labels,  
25 publications, brochures, and other written materials intended for consumers and the general public,  
26 that the Up & Up APAP was safe to human health and the environment, effective, fit, and proper  
27 for their intended use. Defendant advertised, labeled, marketed, and promoted the Up & Up APAP,  
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1 representing the quality to consumers and the public in such a way as to induce their purchases or  
2 use, thereby making an express warranty that the Up & Up APAP would conform to the  
3 representations.

4 105. The representations about the Up & Up APAP, as set forth herein, contained or  
5 constituted affirmations of fact or promises made by the seller to the buyer, which related to the  
6 goods and became part of the basis of the bargain, creating an express warranty that the goods  
7 would conform to the representations.

8 106. Defendant breached express representations and warranties made to Plaintiff  
9 Mother, with respect to the Up & Up APAP, including the following:

- 10 a. Defendant represented through its labeling, advertising, and marketing materials  
11 that the Up & Up APAP was safe, and intentionally withheld and concealed  
12 information about the risks of serious injury associated with use of APAP and by  
13 expressly limiting the risks associated with use within its warnings and labels; and  
14 b. Defendant represented that the Up & Up APAP was safe for use and intentionally  
15 concealed information that demonstrated that APAP carries the significantly  
16 increased risk of causing neurodevelopmental disorders in children through  
17 prenatal exposure to APAP, and that the Up & Up APAP, therefore, was not safer  
18 than alternatives available on the market.

19 107. Plaintiff Mother detrimentally relied on the express warranties and representations  
20 of Defendant concerning the safety and/or risk profile of APAP in deciding to purchase the Up &  
21 Up APAP. Plaintiff Mother reasonably relied upon Defendant to disclose known defects, risks,  
22 dangers, and side effects of APAP. Plaintiff Mother would not have purchased or used the Up &  
23 Up APAP had Defendant properly disclosed the risks associated with the Up & Up APAP, either  
24 through advertising, labeling, or any other form of disclosure.

25 108. Plaintiff Mother had no knowledge of the falsity or incompleteness of Defendant's  
26 statements and representations concerning the Up & Up APAP.  
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1           109. Plaintiff Mother used and/or was exposed to APAP as researched, developed,  
2 designed, tested, manufactured, inspected, labeled, distributed, packaged, marketed, promoted,  
3 sold, or otherwise released into the stream of commerce by Defendant.

4           110. Had the warnings, labels, advertisements, or promotional material for the Up & Up  
5 APAP accurately and adequately set forth the true risks associated with the use of such Products,  
6 including Plaintiffs' injuries, rather than expressly excluding such information and warranting that  
7 the Up & Up APAP was safe for their intended use, Plaintiffs could have avoided the injuries  
8 complained of herein.

9           111. As a direct and proximate result of Defendant's breach of express warranty,  
10 Plaintiffs have suffered permanent injuries, significant pain and suffering, emotional distress, lost  
11 wages and earning capacity, and diminished quality of life. Plaintiffs respectfully seek all damages  
12 to which they may be legally entitled.

13                           **COUNT IV: BREACH OF IMPLIED WARRANTY**

14           112. Plaintiffs incorporate by reference the allegations in all prior paragraphs.

15           113. At all material times, Defendant manufactured, marketed, sold, distributed, and  
16 otherwise placed the Up & Up APAP into the stream of commerce.

17           114. At all material times, Defendant intended for the Up & Up APAP to be consumed  
18 and ingested by pregnant women, like Plaintiff Mother; and Defendant impliedly warranted that  
19 the Up & Up APAP and its component parts were of merchantable quality, safe, fit for such use,  
20 and adequately tested.

21           115. Defendant was aware that consumers, including Plaintiff Mother, would consume  
22 and ingest the Up & Up APAP as directed by the Products' labels and promotional materials.  
23 Therefore, Plaintiff Mother was a foreseeable user of the Up & Up APAP.

24           116. But Defendant failed to disclose that APAP has dangerous propensities when used  
25 as intended and that use of the Up & Up APAP carries an increased risk of developing severe  
26 injuries, including Plaintiff Child's injuries.  
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1           117. The Up & Up APAP was expected to reach, and did in fact reach consumers,  
2 including Plaintiff Mother, without substantial change in the condition in which they were  
3 manufactured and sold by Defendant.

4           118. Plaintiff Mother was an intended beneficiary of the implied warranties made by  
5 Defendant to purchasers of the Up & Up APAP.

6           119. In reliance upon Defendant's implied warranties, Plaintiff Mother used the Up &  
7 Up APAP as indicated, and in the foreseeable manner normally intended, recommended,  
8 promoted, and marketed by Defendant.

9           120. Defendant breached its implied warranties to Plaintiffs in that the Up & Up APAP  
10 was not of merchantable quality, nor were they safe or fit for their intended use or adequately  
11 tested.

12           121. The harm caused by the Up & Up APAP far outweighed their benefit, rendering  
13 the Up & Up APAP more dangerous than an ordinary consumer or user would expect and more  
14 dangerous than alternative products.

15           122. As a direct and proximate result of Defendant's breach of express warranty,  
16 Plaintiffs have suffered permanent injuries, significant pain and suffering, emotional distress, lost  
17 wages and earning capacity, and diminished quality of life. Plaintiffs respectfully seek all damages  
18 to which they may be legally entitled.

19           **COUNT V: VIOLATION OF CONSUMER PROTECTION LAWS**

20           123. Plaintiffs incorporate by reference the allegations in all prior paragraphs.

21           124. Plaintiff Mother purchased and used the Up & Up APAP for primarily personal use  
22 and pain relief during pregnancy, thereby suffering ascertainable losses as a result of Defendant's  
23 actions in violation of the consumer protection laws.

24           125. Had Defendant not engaged in the deceptive conduct described in this Complaint,  
25 Plaintiff would not have purchased and/or paid for the Up & Up APAP, and Plaintiffs would not  
26 have incurred related injury medical costs.  
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126. Defendant engaged in wrongful conduct while at the same time obtaining under false pretenses moneys from Plaintiff for the Up & Up APAP. Those moneys would not have been paid had Defendant not engaged in unfair and deceptive conduct.

127. Defendant engaged in the following unfair methods of competition or deceptive acts or practices, which are proscribed by law:

A. representing that goods or services have characteristics, ingredients, uses, benefits, or qualities they do not have;

B. advertising goods or services with the intent not to sell them as advertised; and

C. engaging in fraudulent or deceptive conduct creating a likelihood of confusion or misunderstanding.

128. Plaintiffs were injured by the cumulative nature of Defendant's conduct. The cumulative effect, directed at patients, physicians, and consumers, was to create demand for and sell the Up & Up APAP. Each aspect of Defendant's conduct combined to artificially create sales of the Up & Up APAP.

129. Defendant had a statutory duty to refrain from unfair or deceptive acts or trade practices in the design, labeling, development, manufacture, promotion, and sale of the Up & Up APAP.

130. Defendant's deceptive, unconscionable, or fraudulent representations and material omissions to consumers, including Plaintiff Mother, constitute unfair and deceptive acts and trade practices in violation of the federal and state consumer protection statutes listed below.

131. Defendant's actions, as complained of in this Complaint, constitute unfair competition or unfair, unconscionable, deceptive, or fraudulent acts or trade practices in violation of the federal and state consumer protection statutes listed below.

132. Defendant has engaged in unfair competition, or unfair or deceptive acts or trade practices, or has made false representations under the following statutes:

- 15 U.S.C. §§ 2301–12 (1982);

- Cal. Bus & Prof. Code § 17200, *et seq.* (Unfair Competition Law (“UCL”));
- Cal. Civ. Code § 17500 (False Advertising Law (“FAL”));

133. Cal. Civ. Code § 1750 *et seq.* (Consumer Legal Remedies Act (“CLRA”)). To protect consumers against unfair, deceptive, fraudulent, and unconscionable trade and business practices, and false advertising, Defendant, as the supplier, manufacturer, advertiser, and seller, is subject to liability under the above legislation enacted against unfair, deceptive, fraudulent, and unconscionable consumer sales practices.

134. By knowingly and falsely representing that the Up & Up APAP was fit to be used for the purposes for which they were intended—when in fact they were defective and dangerous—and by other acts alleged, Defendant violated the above statutes, enacted to protect consumers against unfair, deceptive, fraudulent, and unconscionable trade and business practices, and false advertising. The UCL prohibits “any unlawful, unfair, or fraudulent business act or practice and unfair, deceptive, untrue, or misleading advertising and any act prohibited by” Section 17500 of the California Business and Professions Code. Section 17500, in turn, prohibits any untrue or misleading statements made in connection with the sale of goods. The CLRA defines as statutorily unlawful certain unfair methods of competition and unfair or deceptive practices. Cal. Civ. Code § 1750 *et seq.*

135. By knowingly and falsely representing that the APAP Products were fit to be used for the purposes for which they were intended—when in fact they were defective and dangerous when used during pregnancy—and by other acts alleged, Defendant violated the above statutes, enacted to protect consumers against unfair, deceptive, fraudulent, and unconscionable trade and business practices, and false advertising.

136. Defendant’s actions and omissions are uncured or incurable, deceptive acts under the above legislation.

137. Defendant had actual knowledge of the defective and dangerous conditions of the Up & Up APAP but failed to take any action to cure such defective and dangerous conditions.

138. Plaintiff Mother relied upon Defendant’s misrepresentations and omissions in determining which Up & Up APAP (if any) to ingest.

139. Defendant's deceptive, unconscionable, or fraudulent representations and material omissions to consumers constituted unfair and deceptive acts and practices.

140. By reason of the unlawful acts in which Defendant engaged, and as a direct and proximate result thereof, Plaintiffs have suffered ascertainable losses and damages.

141. As a direct and proximate result of Defendant's violations of the above-listed legislation, Plaintiffs have sustained economic losses and other damages and are entitled to statutory and compensatory damages in an amount to be proven at trial.

**COUNT VI: NEGLIGENT MISREPRESENTATION**

142. Plaintiffs incorporate by reference the allegations in all prior paragraphs.

143. Defendant had a duty to accurately and truthfully represent to consumers, including Plaintiff Mother, and the public that the Up & Up APAP had not been adequately tested and found to be a safe and effective treatment for pregnant women. Defendant breached that duty as its representations were false.

144. Defendant failed to exercise ordinary care in the representations concerning the Up & Up APAP while Defendant was involved in its manufacture, sale, testing, quality assurance, quality control, and distribution in interstate commerce, because Defendant negligently misrepresented the Up & Up APAP's high risk of unreasonable and dangerous adverse side effects.

145. Defendant also breached its duty in representing to Plaintiff Mother that the Up & Up APAP had no serious side effects when ingested during pregnancy.

146. As a foreseeable, direct, and proximate result of Defendant's negligent misrepresentations, Defendant knew or had reason to know that the Up & Up APAP had been insufficiently tested or had not been tested at all; and that they lacked adequate and accurate warnings, and created a high risk, or a higher than acceptable reported and represented risk, of adverse side effects. Those side effects include neurodevelopmental disorders in children, such as ASD.

147. As a direct and proximate result of Defendant's breach of express warranty, Plaintiffs have suffered permanent injuries, significant pain and suffering, emotional distress, lost

wages and earning capacity, and diminished quality of life. Plaintiffs respectfully seek all damages to which they may be legally entitled.

### **PUNITIVE DAMAGES**

148. Plaintiffs incorporate by reference the allegations in all prior paragraphs.

149. Defendant failed to adequately test and study the Up & Up APAP to determine and ensure that the Up & Up APAP was safe and effective prior to releasing them for sale for human consumption.

150. Further, Defendant continued to manufacture and sell the Up & Up APAP after obtaining knowledge and information that they were defective and unreasonably unsafe in that they did not include adequate warnings.

151. Defendant was aware of the probable consequences of the dangerous and defective product, including the risk of neurodevelopmental disorders in children, such as ASD, when they suffered prenatal exposure.

152. At all material times, Defendant knew or should have known that the Up & Up APAP was inherently dangerous with respect to the following: the risk of neurodevelopmental disorders in children, such as ASD, when they suffered prenatal exposure; pain and suffering; loss of life's enjoyment; and unsuccessful treatments to cure the conditions proximately related to the use of the Up & Up APAP, as well as the other permanent and lasting severe personal injuries.

153. Defendant's misrepresentations included knowingly withholding material information from consumers and the public, including Plaintiff Mother, concerning the safety and efficacy of the Up & Up APAP, which deprived Plaintiff Mother of vitally necessary information with which to make a fully informed decision about whether to use the Up & Up APAP.

154. At all material times, Defendant also knew and recklessly and/or intentionally disregarded the fact that the Up & Up APAP can cause debilitating and life-altering side effects with greater frequency than safer alternative methods, products, and/or treatments. But Defendant recklessly failed to advise the medical community and the general public, including Plaintiff Mother, of that fact.

1           155. At all material times, Defendant intentionally misstated and misrepresented data;  
2 and Defendant continues to misrepresent data so as to minimize the perceived risk of injuries and  
3 the rate of complications caused by or associated with the Up & Up APAP.

4           156. Notwithstanding the foregoing and the growing body of knowledge and  
5 information regarding the true and defective nature of the Up & Up APAP, with its increased risk  
6 of side effects and serious complications, Defendant continues to aggressively market the Up &  
7 Up APAP to consumers, including the pregnant community at large, without disclosing the true  
8 risk of the complications and side effects.

9           157. When Plaintiff Mother consumed the Up & Up APAP and since then, Defendant  
10 has known the Up & Up APAP was defective and unreasonably dangerous without an adequate  
11 warning. But Defendant continued to manufacture, produce, assemble, market, distribute, and sell  
12 the Up & Up APAP to the pregnant community so as to maximize sales and profits at the expense  
13 of the health and safety of expecting mothers in a conscious, reckless, and/or intentional disregard  
14 of the likely and foreseeable harm caused by the Up & Up APAP to members of the public,  
15 including Plaintiffs.

16           158. At all material times, Defendant has concealed and/or failed to disclose to the public  
17 the serious risks and the potential complications associated with the Up & Up APAP, so as to  
18 ensure continued and increased sales and profits and to the detriment of the public, including  
19 Plaintiffs.

20           159. Defendant's acts and omissions are of such character and nature so as to entitle  
21 Plaintiffs to an award of punitive damages in accordance with applicable statutory and common  
22 law. Defendant's conduct shows willful misconduct, malice, fraud, wantonness, oppression, or  
23 that entire want of care, raising the presumption of conscious indifference to consequences, thereby  
24 justifying an award of punitive damages.

25           WHEREFORE, Plaintiffs demand judgment against Defendant individually, and jointly  
26 and severally. Plaintiffs also request compensatory damages, punitive damages, or enhanced  
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compensatory damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

**PRAYER FOR RELIEF**

Plaintiffs demand judgment against Defendant, individually, and jointly and severally, and prays for the following relief in accordance with applicable law and equity:

- i. Compensatory damages to Plaintiffs for past, present, and future damages, including pain and suffering for severe and permanent personal injuries sustained by Plaintiffs, permanent impairment, mental pain and suffering, loss of enjoyment of life, health and medical care costs, economic damages, together with interest and costs as provided by law;
- ii. Restitution and disgorgement of Defendant's profits;
- iii. Applicable statutory penalties;
- iv. Punitive or enhanced compensatory damages;
- v. Reasonable attorneys' fees as provided by law;
- vi. Past and future costs of all proceedings;
- vii. All ascertainable economic damages;
- viii. Prejudgment interest on all damages as allowed by law; and
- ix. Such other and further relief as this Court deems just and proper.

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**DEMAND FOR JURY TRIAL**

Plaintiffs hereby demands a trial by jury on all issues so triable.

Dated: June 17, 2022

Respectfully submitted,

/s/ Keith A. Custis

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